UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

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Re: Case No. 21-6203*, Children's Health Defense, et al v. FDA, et al*
Originating Case No. : 1:21-cv-00200

Dear Counsel,

The Court issued the enclosed opinion today in this case.

Enclosed are the court's unpublished opinion and judgment, entered in conformity with Rule 36, Federal Rules of Appellate Procedure.

Sincerely yours,

s/Cathryn Lovely
Opinions Deputy

cc: Ms. LeAnna Wilson

Enclosures

Mandate to issue

NOT RECOMMENDED FOR PUBLICATION
File Name: 22a0276n.06

Case No. 21-6203

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
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CHILDREN'S HEALTH DEFENSE; AMY MILLER,

Plaintiffs - Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, M.D.,

Defendants - Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE

OPINION

Before: GIBBONS, ROGERS, and MURPHY, Circuit Judges.

JULIA SMITH GIBBONS, Circuit Judge. Children's Health Defense ("CHD")[1] and Amy Miller, collectively "plaintiffs," sued the Food & Drug Administration and its acting commissioner Dr. Janet Woodcock, collectively "FDA," for "failing to carry out its mission." DE 19, Am. Compl., Page ID 857. Plaintiffs, attempting to represent adult military servicemembers, sought a "stay" of FDA's licensure of Pfizer's Comirnaty COVID-19 vaccine and FDA's reauthorization of the Pfizer-BioNTech emergency use authorization. The district court denied plaintiffs' motion and dismissed the case for lack of subject matter jurisdiction. We affirm because plaintiffs lack standing.

[1] CHD is a nonprofit organization that seeks to end "childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and establish safeguards so this never happens again." DE 26, Decl., Page ID 1057.

I

The Public Health Service Act requires an approved biologics license application from FDA before companies introduce biological products, like vaccines, into interstate commerce. *See* 42 U.S.C. § 262(a)(1)(A), (i)(1). Separately, the Federal Food, Drug, and Cosmetic Act allows FDA to authorize biological products that are "intended for use in an actual or potential emergency," "[n]otwithstanding" the Public Health Service Act's licensing provisions. 21 U.S.C. § 360bbb-3(a)(1). The Secretary of Health and Human Services may issue such emergency use authorizations ("EUAs") under limited circumstances, which permit the immediate use of a vaccine without first obtaining a biologics license. *Id*. § 360bbb-3(c). FDA's licensing authority under 21 U.S.C. § 262 and its EUA authority under 21 U.S.C. § 360bbb-3 are independent of each other; FDA's licensing authority does not affect its EUA authority and vice versa. *Compare* 21 U.S.C. § 360bbb-3(a)(1), (*l*), (k), *with* 42 U.S.C. § 262(g).

In January 2020, the Secretary of Health and Human Services declared a public emergency in response to the COVID-19 pandemic. Pharmaceutical companies, including Pfizer, Moderna, and Johnson & Johnson, began researching and developing potential vaccines. In December 2020, FDA issued an EUA for the Pfizer-BioNTech vaccine for the prevention of COVID-19 in individuals age sixteen and older. FDA has since reissued the EUA several times to update the vaccine's labeling with additional safety information and to incorporate amendments to the EUA that have, for example, expanded the age groups eligible to receive the vaccine.

In May 2021, CHD filed a Citizen Petition with FDA requesting that it refrain from licensing COVID-19 vaccines and revoke the prior EUAs for COVID-19 vaccines. Then, on August 9, 2021, the Secretary of Defense advised all Department of Defense ("DOD") employees that "he would 'seek the President's approval to make the [COVID-19] vaccines mandatory no

later than mid-September, or immediately upon the [FDA's] licensure, whichever comes first.'" *Child.'s Health Def. v. FDA*, __ F. Supp. 3d __, 2021 WL 5756085, at *1 (E.D. Tenn. Nov. 30, 2021) (citation omitted).

On August 23, 2021, FDA licensed Pfizer's Comirnaty vaccine for use in individuals age sixteen and older and simultaneously reissued an EUA for the Pfizer-BioNTech vaccine. FDA described Comirnaty as "interchangeable" with Pfizer-BioNTech but still "legally distinct" because the two are subject to separate statutory regimes. FDA explained it maintained the Pfizer-BioNTech EUA, despite Comirnaty's licensure, because there was "no adequate, approved, available alternative" to the EUA product with enough doses "available for distribution" to all individuals over age sixteen and the licensed vaccine had not been approved for children under sixteen or for booster doses. DE 19-1, Pfizer EUA, Page ID 900, n.9.

CHD, "on behalf of its members who have been affected by [FDA's] actions," and Miller sued, asking the district court to enjoin FDA from licensing Comirnaty and extending the Pfizer-BioNTech EUA. DE 19, Am. Compl., Page ID 857. Plaintiffs claim that FDA's licensure of Pfizer's Comirnaty and simultaneous extension of the Pfizer-BioNTech EUA violates federal law because EUA designations can only occur when the Secretary finds "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." 21 U.S.C. § 360bbb-3(c)(3). They allege FDA failed to articulate a satisfactory explanation for its decision to extend the Pfizer-BioNTech EUA once Comirnaty was licensed, thereby making an arbitrary and capricious decision in violation of the Administrative Procedure Act. As a remedy, plaintiffs seek to have FDA's decisions to license Comirnaty and reauthorize the Pfizer-BioNTech EUA "vacate[d] and remand[ed]." DE 19, Am. Compl., Page ID 867.

In support of their claims, plaintiffs attach the declarations of fifteen CHD members who were or are serving in the United States military. These individuals generally allege that unvaccinated servicemembers who refuse to comply with the military's vaccine requirements are facing or will face adverse consequences. As the district court explained, the declarants identify "various objections to receiving the vaccine, including religious based objections and concerns regarding the effect the vaccine might have on their ability to have children," and many express fears that "they are in jeopardy of being discharged from the military and losing retirement benefits and their future careers" if they remain unvaccinated. *Child.'s Health Def.*, 2021 WL 5756085, at *2. "Plaintiffs also include an affidavit from CHD's general counsel, Mary S. Holland, who states that the interests of the declarants who 'CHD protects are clearly related to CHD's mission and overarching goals as an organization.'" *Id*. (citation omitted).

Plaintiffs moved to stay FDA's licensure of the Comirnaty vaccine and FDA moved to dismiss CHD's complaint for lack of jurisdiction. The district court found that plaintiffs lacked standing and granted FDA's motion to dismiss and denied plaintiffs' motion to stay.

II

The district court dismissed plaintiffs' complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), a decision we review de novo. *Ass'n of Am. Physicians & Surgeons v. FDA (AAPS)*, 13 F.4th 531, 535 (6th Cir. 2021).

A

An organization can satisfy Article III's standing requirements by suing on its own behalf, called "organizational standing," or by suing on behalf of its members, called "associational" or "representative" standing. *See Online Merchants Guild v. Cameron*, 995 F.3d 540, 547 (6th Cir.

2021); *AAPS*, 13 F.4th at 537. The district court correctly found that CHD lacks both organizational and associational standing.

"To establish direct standing to sue in its own right, an organizational plaintiff" like CHD "must demonstrate that the 'purportedly illegal action increases the resources the group must devote to programs independent of its suit challenging the action.'" *Online Merchants*, 995 F.3d at 547 (citation omitted). On appeal, plaintiffs claim "the amended complaint sufficiently pleads that challenging the FDA's conduct drained substantial CHD resources." CA6 R. 13, Appellant Br., at 20 (formatting altered). Plaintiffs base this argument on the resources CHD allegedly expended in filing the Citizen Petition with FDA. But these allegations are not sufficiently pled in the amended complaint. The amended complaint's only reference to CHD's Citizen Petition is in paragraph seventeen, which states—in its entirety—that "CHD filed a Citizen Petition with the FDA (Exh. 1) on May 16, 2021, asking the FDA to refrain from licensing COVID vaccines and to revoke EUAs for the three existing COVID vaccines. Individuals have submitted over 30,000 comments on this petition." DE 19, Am. Compl., Page ID 859. This is not an assertion that CHD was injured by having to divert resources to oppose FDA's actions. The only mention of diverting resources appears in plaintiffs' district court reply brief. But under a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction that, as here, is a facial attack, courts are limited to assessing the sufficiency of plaintiffs' complaint. *Cartwright v. Garner*, 751 F.3d 752, 759–60 (6th Cir. 2014). Plaintiffs failed to sufficiently plead that CHD has organizational standing.

B

"Even where an organizational plaintiff lacks standing to sue in its own right, it may sue on behalf of its members if 'its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor

the relief requested requires the participation of individual members in the lawsuit.'" *Online Merchants*, 995 F.3d at 549 (citation omitted). CHD fails to satisfy the first two elements of associational standing.[2]

First, CHD cannot show "the interests it seeks to protect are germane" to its "purpose" as an organization. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *AAPS*, 13 F.4th at 537. In *Hunt*, the Supreme Court found the Washington State Apple Advertising Commission's "purpose is the protection and promotion of the Washington apple industry," which encompasses litigation to benefit this "specialized segment of the [Washington] economic community." 432 U.S. at 344. Similarly, in *Online Merchants*, we found the Online Merchants Guild's suit "addressing price gouging as it relates to eCommerce falls within the scope of the Guild's mission, 'to advocate for a free and fairly-regulated online marketplace.'" 885 F.3d at 549 (citation omitted).

Here, CHD's purpose is detached from the interests at stake in the complaint. Plaintiffs' appellate brief claims the "protection of military service member's [sic] rights to refuse or consent to COVID vaccines . . . is a core thrust of the CHD's organizational purpose." CA6 R. 13, Appellant Br., at 34. But CHD's stated mission is to end "childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and establish safeguards so this never happens again." DE 26, Decl., Page ID 1057. The connection between a suit concerning the vaccination of adult military members and an organization committed to protecting children's health is too attenuated to establish CHD's "stake in the resolution of the

[2] The Supreme Court has explained that "individual participation" is usually unnecessary "when an association seeks prospective or injunctive relief for its members." *United Food & Com. Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996). Because CHD seeks a "stay" of FDA's actions, a form of injunctive relief, this suit likely does not require participation by individual CHD members.

dispute" and "position to serve as [FDA's] natural adversary." *United Food & Com. Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 555–56 (1996).

Second, CHD cannot show that its members have standing in their own right. To establish associational standing based on members' standing, an organization must identify a member who has suffered, or imminently will suffer, an injury in fact that is fairly traceable to the challenged conduct and redressable by the relief sought. *See AAPS*, 13 F.4th at 543. Even if CHD could identify a member who has suffered or imminently will suffer an injury in fact, it cannot show the requisite causation or redressability.

Causation. Plaintiffs fail to show causation. Causation requires a causal connection between the alleged injuries and the conduct complained of. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). The injuries must be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." *Id*. (citation omitted). Here, plaintiffs' alleged injuries are not fairly traceable to FDA's actions. The military's vaccination requirements, and the alleged possible consequences from failing to comply, stem from DOD decisionmakers. FDA has not imposed any kind of mandate affecting the declarants, and DOD is a third party not before this court.

When a third party causes plaintiffs' alleged harm, the plaintiffs must show the third party's "choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Parsons v. DOJ*, 801 F.3d 701, 713 (6th Cir. 2015) (quoting *Lujan*, 504 U.S. at 562). Plaintiffs claim this requirement is satisfied because FDA and DOD are not independent; rather, they act jointly under a single executive branch. But even when two executive agencies are implicated, traditional third-party causation principles apply. *See Bennett v. Spear*, 520 U.S. 154, 168–71 (1997).

Plaintiffs fail to explain how their alleged injuries are the direct result of the specific FDA action challenged. FDA has not required the general public to be vaccinated, FDA has not required military servicemembers to be vaccinated, and FDA does not control the military. Plaintiffs challenge FDA's licensure and reauthorization of Pfizer's vaccines; this is in no way tied to military leadership's implementation of the vaccination requirements that caused plaintiffs' alleged injuries. Plaintiffs cite no authority requiring that we construe the action of one agency as tantamount to another's, even when both agencies fall within the same branch of government. Further, plaintiffs cite no authority that connects DOD's decision to implement a vaccine requirement to FDA's decisions about licensure and reauthorization.

Redressability. Besides failing to show causation, plaintiffs fail to show redressability. "[I]t must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan*, 504 U.S. at 561 (citation omitted). Here, plaintiffs must show that ordering FDA to revoke its licensure of Comirnaty and its reauthorization of the Pfizer-BioNTech EUA would redress their alleged injuries from DOD's vaccination requirements. Plaintiffs have failed to do so. On appeal, plaintiffs argue their injuries are redressable because DOD relied on FDA's "misleading representations regarding the 'interchangeability'" between Pfizer's licensed Comirnaty vaccine and reauthorized Pfizer-BioNTech EUA. CA6 R. 13, Appellant Br., at 40. But this does not explain how a "stay" would redress plaintiffs' alleged injuries.

As the district court recognized, if the Comirnaty license is revoked, the Pfizer-BioNTech EUA remains in place and that vaccine is available for administration. DOD, a third party, can continue requiring vaccination of servicemembers as a condition of employment, and it can require vaccination regardless of whether the vaccine is distributed pursuant to a license or EUA. *See* 10 U.S.C. § 1107a. Moreover, DOD could administer COVID-19 vaccines manufactured by other

companies with licenses and EUAs not challenged here. Because DOD's vaccine mandate is not tied to FDA's actions, plaintiffs' requested relief will not redress their alleged injuries.

Because CHD's members would not otherwise have standing to sue in their own right and the interests at stake are not germane to the organization's purpose, CHD lacks associational standing.

C

Miller, a member of CHD and the only individual plaintiff, likewise lacks standing. Her only allegation of harm is that she "is at imminent risk of immediate harm from FDA's actions to both license and contemporaneously authorize Pfizer vaccines against COVID." DE 19, Am. Compl., Page ID 857. She fails to explain what specific harm she faces and how it can be fairly traced to FDA's conduct. She does not claim she is subject to any vaccine mandate or that she will face penalties for failing to get vaccinated. Her allegation that she is at "imminent risk" of unspecified harm is insufficient to establish injury in fact because it is neither concrete nor particularized.

III

The district court dismissed plaintiffs' amended complaint. On appeal, plaintiffs claim this is reversible error because leave to amend a pleading should be freely granted. A district court does not abuse its discretion by dismissing a complaint without leave to amend when no leave was sought. *See Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 438 (6th Cir. 2008). As this court has explained, "it is not the district court's role to initiate amendments." *Id*. "The argument that the district court should have rescued Plaintiffs by *sua sponte* offering leave to amend the complaint is simply misplaced." *Id*. Plaintiffs never moved for leave to file a second amended complaint nor did they file a proposed second amended

complaint. *See Crosby v. Twitter, Inc.*, 921 F.3d 617, 628 (6th Cir. 2019). Moreover, plaintiffs received ample notice that their original complaint failed to sufficiently allege harm when the district court denied their motion for a temporary restraining order. Plaintiffs have had "ample opportunities to present their case." *Stewart v. IHT Ins. Agency Grp., LLC*, 990 F.3d 455, 457 n.* (6th Cir. 2021). We affirm the district court's decision to dismiss plaintiffs' complaint without sua sponte offering leave to amend.

IV

We affirm the district court's judgment dismissing plaintiffs' amended complaint because neither CHD nor Miller has standing.

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FOR THE SIXTH CIRCUIT

No. 21-6203

CHILDREN'S HEALTH DEFENSE; AMY MILLER,

Plaintiffs - Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, M.D.,

Defendants - Appellees.

FILED
Jul 12, 2022
DEBORAH S. HUNT, Clerk

Before: GIBBONS, ROGERS, and MURPHY, Circuit Judges.

JUDGMENT

On Appeal from the United States District Court
for the Eastern District of Tennessee at Chattanooga.

THIS CAUSE was heard on the record from the district court and was submitted on the briefs without oral argument.

IN CONSIDERATION THEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTERED BY ORDER OF THE COURT

Deborah S. Hunt, Clerk